JUL 2 6 2001

510(k) Summary of Safety and Effectiveness

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92. This device is a Class II device per 21 CFR 864.9205, nonelectromagnetic blood and plasma warming device; henceforth referred to as the Thermal Angel™.

Submitter:

Estill Medical Technologies, Inc
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Contact:

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Date Prepared: July 23, 2001

Trade/Proprietary Name: Thermal Angel™ model 200 Blood/Fluid Warmer

Classification Name: Warmer, blood, nonelectromagnetic

Predicate Devices: Augustine Medical Bair Hugger™ Blood/Fluid Warmer, Level1 Technologies, Inc Hotline™ Fluid Warmer, Baxter Thermacyl™ Blood/Fluid Warmer, Thermal Angel™ (K984640)

Description of Device:

The Thermal Angel™ model 200 Blood/Fluid Warmer consists of a single unit that is placed between a standard IV drip set and a standard IV extension set. Thermal Angel™ is designed to warm blood, blood products and intravenous fluids at flow rates of up to and including 200 ml/min. Thermal Angel™ will deliver temperatures of 38°C (100.4°F). While the temperature will drop immediately after making major changes in flow rate, it will drop only a few degrees and return smoothly and within seconds, to 38°C (100.4°F).

Thermal Angel's™ fluid path is sterile and nonpyrogenic, and the entire warming unit is disposable after use. Thermal Angel™ is battery operated, powered by a 12V DC system. Blood, blood products and intravenous fluids travel through stainless steel tubing which is surrounded by a heating blanket and heated by electrical resistance. The temperature of the device is accurately controlled by the device's electronics. The electrical requirements are designed in accordance with UL 2601 and CSA 601.

Statement of Intended Use:

The Thermal Angel™ model 200 Blood/Fluid Warmer is indicated for the warming of blood, blood products and intravenous fluids prior to administration. It is intended to be used by healthcare professionals in clinical and field environments.

Comparison of the Technological Characteristics of the New Device and the Predicate Devices:

The Thermal Angel™ model 200 Blood/Fluid Warmer is substantially equivalent to the Augustine Medical Bair Hugger ™ Blood/Fluid Warmer (K973741), the Baxter Thermacyl™ Blood/Fluid Warmer (K770232), the Level1 Technologies, Inc Hotline™ Fluid Warmer (K911383) and the Thermal Angel™ (K984640). Comparisons of technological features are on the following page.

Discussion of Nonclinical Studies:

Laboratory evaluations have been conducted to evaluate the hemolytic effect of the Thermal Angel™ model 200 Blood/Fluid Warmer during flow, stop flow, and high flow rates. Hemolysis was shown to be none or not clinically significant.

Conclusion:

The Thermal Angel™ model 200 Blood/Fluid Warmer has similar technological characteristics and the same intended use as devices currently on the market. Therefore, because of the similarities to the predicate devices, Estill Medical Technologies, Inc., believes these modifications do not raise any new safety or effectiveness issues.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 26 2001

Mr. Daniel T. Kistner
QA/Regulatory Affairs
Estill Medical Technologies, Incorporated
4144 North Central Expressway, Suite 260
Dallas, Texas 75204

Re: K012031
Trade/Device Name: Modification To Thermal Angel
Regulation Number: 864.9205
Regulatory Class: II
Product Code: BSB and LGZ
Dated: May 31, 2001
Received: June 28, 2001

Dear Mr. Kistner:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements

concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): ~~K984040~~ K012031

Device Name: Thermal Angel™ model 200 Blood and Fluid Warmer

Indications for Use: Thermal Angel™ model 200 Blood and Fluid Warmer is an in-line, intravenous blood and fluid warmer. Thermal Angel™ is indicated for use whenever introduction of normothermic, parenteral (intravenous or irrigation) fluids are desired or indicated, whether in field or clinical settings.

(Attachment A)

(Please do not write below this line—Continue on another page if needed.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____
(21 CFR 801.109) Optional format 1-2-96

(Division Sign-Off)
Division of Dental, Infection Control, and General Medical Devices

510(k) Number _____

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K012031